Dated: February 4, 1998.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 98–3190 Filed 2–4–98; 12:45 pm]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98F–0057]

Ciba Specialty Chemicals Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Ciba Specialty Chemicals Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of calcium bis[monoethyl(3,5-di-*tert*-butyl-4-hydroxybenzyl)phosphonate] as a stabilizer for polyethylene phthalate polymers intended for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 8B4578) has been filed by Ciba Specialty Chemicals Corp., 540 White Plains Rd., Tarrytown, NY 10591–9005. The petition proposes to amend the food additive regulations in § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) to provide for the safe use of calcium bis[monoethyl (3,5-di-*tert*-butyl-4-hydroxybenzyl)phosphonate] as a stabilizer for polyethylene phthalate polymers, complying with 21 CFR 177.1630, intended for use in contact with food.

The agency has determined under 21 CFR 25.32(i) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: January 22, 1998.

Laura M. Tarantino,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 98–2909 Filed 2–5–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0003]

FDA Modernization Act of 1997: Guidance for the Device Industry on Implementation of Highest Priority Provisions; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''FDA Modernization Act of 1997: Guidance for the Device Industry on Implementation of Highest Priority Provisions; Availability.'' This guidance, generally referred to as the ''Day-1 guidance'' summarizes FDA's strategy for implementing the highest priority provisions of the FDA Modernization Act of 1997 (FDAMA) as it relates to the regulation of medical devices. The agency requests comments on this guidance.

DATES: Submit written comments by May 7, 1998.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Submit written requests for single copies of the guidance entitled ''FDA Modernization Act of 1997: Guidance for the Device Industry on Implementation of the Highest Priority Provisions'' to the Division of Small Manufacturers Assistance, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ–1), Food and Drug Administration, 1350 Picard Dr., Rockville, MD 20850, 301–443–4690.

SUPPLEMENTARY INFORMATION:

I. Background

The ''Day-1 guidance'' announced in this document summarizes FDA's strategy for implementing the highest priority provisions of the FDAMA (Pub. L. 105–115) as it relates to the regulation of medical devices. FDA identified these provisions as being of the highest priority for implementation because: (1) They become effective on or before February 19, 1998, the general effective date of the act; (2) they are expected to impact a large number of products/applications; or (3) they are of high interest to the device community. Unless an alternative method of implementation is specified in the statute, FDA generally plans to issue individual guidance documents to implement these provisions of the new law. The highest priority provisions of FDAMA identified in the guidance, and related sections in FDAMA, are:

(1) Early collaboration on data requirements for clinical studies (sections 201 and 205),

(2) Premarket approval application (PMA) collaborative review process (section 209),

(3) Scope of review: labeling claims for PMA's (section 205),

(4) PMA supplements for manufacturing changes (section 205),

(5) Premarket notification exemptions (section 206),

(6) Evaluation of automatic class III designation (section 207),

(7) Device standards (section 204),

(8) Scope of review: labeling claims for 510(k)'s (section 205),

(9) 90-Day review of 510(k)'s (section 209),

(10) Device tracking (section 211),

(11) Postmarket surveillance (section 212), and

(12) Dispute resolution (section 404).

The ''Day-1 guidance'' provides a section-by-section summary of each of these statutory provisions and describes FDA's general approach to implementing each such provision.

In accordance with FDA's Good Guidance Practices (62 FR 8961, February 27, 1997), this Level 1 guidance is being issued without prior public comment because it affects immediate implementation of new statutory requirements. Comments and suggestions regarding this guidance may be submitted by May 7, 1998. Unless specified otherwise, other guidances referenced in this guidance will also be issued as Level 1 guidances that become effective upon publication, with the opportunity to submit comments to the agency during the implementation stage.

This guidance represents the agency's current thinking on the implementation